BeneCheck™

Blood Glucose Monitoring System

User's Manual

BeneCheck

GLU

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Chapter 1 BeneCheck Blood Glucose Monitoring System

1.1 Introduction

Thank you for choosing BeneCheck Blood Glucose Monitoring System. The BeneCheck Blood Glucose Monitoring System is designed by General Life Biotechnology Co., Ltd and marketed all over the world.

The BeneCheck Blood Glucose Monitoring System provides you with accurate, plasma-calibrated results based on electrochemical sensor technology and the superior capillary sampling. The BeneCheck Blood Glucose Monitoring System requires only a small amount of blood, the blood glucose level is precisely calculated and displayed in 10 seconds.

Intended Use :
The BeneCheck Blood Glucose Monitoring System is designed to measure the blood glucose levels in whole blood. The test strips are for testing outside the body (in vitro diagnostic use). It should be used only for testing blood glucose with fresh capillary whole blood samples. The system is suitable for diabetics to monitoring their blood glucose at home by themselves and also can be used at clinical sites by healthcare professionals to test the blood glucose levels of patients.

The BeneCheck Blood Glucose Monitoring System is calibrated by J&J DT60 Analyzer (Kodak EKTACHEM DT60 Analyzer) using venous plasma. The DT60 Analyzer is calibrated by VITROS DT calibrators which were referenced to NIST SRM917b and AACC/CDC (Hexokinase/G6PDH).

Please read the entire USER'S MANUAL carefully before using the BeneCheck Blood Glucose Monitoring System to test your blood glucose levels. This USER'S MANUAL guides you through the operation procedures with illustrated directions and help you find the required informations.

WARNING :
Please carefully read the instructions in this USER'S MANUAL and become familiar with the test procedures before using the system to test blood glucose level. User should do the quality check and consult with a diabetic healthcare professional before doing any important medical decision.

1.2 Contents of the Kit
Please check the whole package for the BeneCheck Blood Glucose Monitoring System. The system includes the following items :

Item No.	Description	Quantity
PD-A016	BeneCheck Blood Glucose Meter	1
PD-A041	BeneCheck Blood Glucose Test Strip (vial)	1
PD-A020	Code Strip	1
PD-F004	BeneCheck Glucose Control Solution	1
PP-E003	BeneCheck Blood Glucose User's Manual	1
PP-E006	BeneCheck Blood Glucose Test Strip Instruction	1
PD-A019	Kit Carrying Bag	1
PD-A015	Lancing Device	1
PD-A018	Lancets (pack) (Manufacturer : For detail information, please refer to inside package.)	1
Optional :	(not included in the standard kit package, please contact your local distiubutor for ordering.)	
BeneCheck Blood Glucose Test Strip		BK-G-S001

1.3 Labelling and Informations

②	Do not re-use	⧖	Use by
☂	Keep dry	📖	Read instructions
☼	Keep away from sunlight	⚠	Caution, consult accompanying documents
Operation 40°C / 10°C	Operation temperature limitation	EC REP	EU Representative
Storage 30°C / 10°C	Storage temperature limitation	REF	Catalogue number (Product number)
CE 0197	CE certification	IVD	In-vitro diagnostic
⬚	Manufactured by	LOT	Lot number

1.4 System Components
Meter (Front Side)
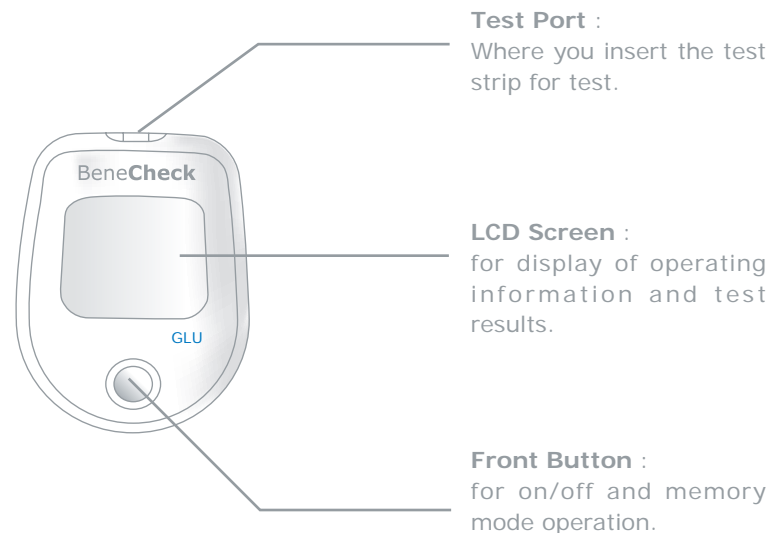
Test Port :
Where you insert the test strip for test.
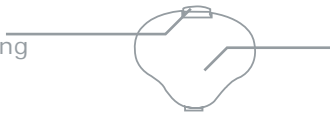
BeneCheck

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LCD Screen :
for display of operating information and test results.

Front Button :
for on/off and memory mode operation.

Meter (Back Side)

Battery Cover Lid :
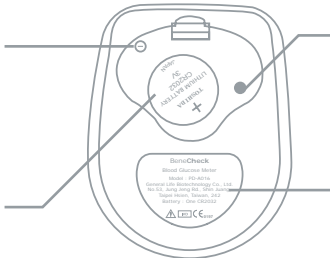Lift upward while replacing the battery.

Battery Cover :
For covering the battery.

Screw :
For holding the meter together, do not open or disassemble the BeneCheck Blood Glucose meter.

Reset Button :
For setup and reset of the meter.

Tag :
Display information about the meter.

Battery :
3V lithium battery(CR2032)

Test Strip

Electronic Contact Bars :
Insert this end of the test strip into the Test Port of the meter to activate it.
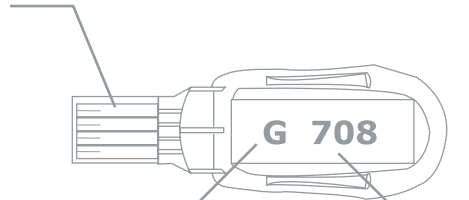
BeneCheck

Sample Inlet :
The inlet where the whole blood or control solution is drawn in. When a blood sample or control solution touches this end, the sample will be sucked into the reaction zone automatically.

Code Strip (Front View)

Contact Bar :
Insert this end into
the Test Port of the
meter.

G 708

Tset Mode

Code Number

Tset Mode :
G - Glucose

2.1 Installing/Replacing the Batteries
A 3-volt lithium battery (CR2032) is included in the meter package. Use only
3V lithium batteries. Do not use or replace the battery with different types of
batteries. Doing so will damage the electronics of the meter.
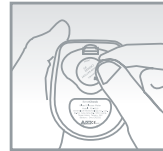
Instructions :

1.

Hold the meter with one hand, slightly lift the back cover lid
to open the back cover.

2.

Insert a new battery in the meter with the "+" side facing
up, you will hear a "beep" sound which indicates that meter
is on.

3. Please back the cover onto the meter.

2.2 Set the Year/Month/Day/Hour/Minute/Temperature unit
After a battery is installed in the meter for the first time (as described in 2.1), the meter goes into setting mode automatically.

The directions to setting mode.
Open the battery cover (on the back of the meter), press the setting button then a number such "08" will blink on screen, which means Year.

Set the Year
1. Press the front button to advance one year until you get a correct year number.
2. After you set the desired year number, press the back setting button again then the meter enters into month setting.

Set the Month
1. Press and release the front button until the correct month appears.
2. Press the setting button and the day segment will start blinking.

Set the Day
1. Press and release the front button until the correct day appears.
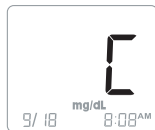2. Press the setting button and hour segment starts blinking.

Set the Hour
1. Press and release the front button until the correct hour appears.
2. Press the setting button and minute segment start blinking.

Set the Minute
1. Press and release the front button until the correct minute appears.
2. Press the setting button and temperature unit (˚C or˚F) starts blinking.

Set the Unit of Temperature
1. Press and release the front button to select the unit of temperature, ˚C or ˚F.
2. Press the setting button when the desired unit is selected. The meter thus completes the setting and turns off automatically.

Note :
Please refer to Chapter 5 for the blood glucose measurement units setting procedure.

2.3 Coding the Meter
The BeneCheck Blood Glucose Meter should be coded before testing with BeneCheck Glucose Test Strips for the first time, or every time a new box of BeneCheck Glucose Test Strips is used. Each vial of test strips has an assigned code number. The code strip is packaged with the test strip in order to calibrate/code the meter. Every time a test strip is inserted, please be sure to check the code number appearing on the screen is the same as the code number marked on the test strip vial.
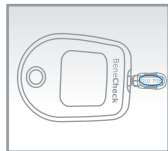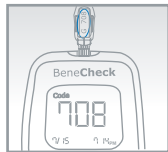
Directions :

1. Check the code number on the code strip is the same as the code number on the test strip vial.
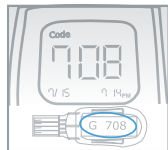
2. Insert code strip into the test port of the meter.

3. Wait for the code number to appear on the screen.

4. Make sure the code number on the screen is the same as the code number on the code strip.
Remove the code strip. "☺" should appear on the screen, indicating that the meter has been coded.

Cautions :
If "E-C" appears on the screen after removing the code strip, there may be a problem with the code strip. Perform the coding again, and if "E-C" continues to appear, please contact the original dealer or supplier for service.
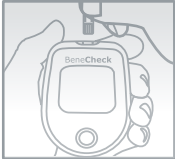
2.4 Control Test
A control solution is used to check the performance of the BeneCheck Blood Glucose Monitoring System, including BeneCheck Blood Glucose Meter, BeneCheck Blood Glucose Test Strip, and the user's operating skill. The system performs adequately if the control test result falls within the indicated control range listed on the test strip vial.

The system should be checked
● When you get the meter for the first time or begin using a new vial of test strip.
● When you suspect that the meter or the test strips are not working properly.
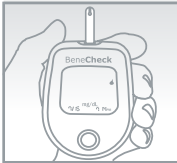
- Any time the blood glucose test results are not consistent with how you feel, or any time you think your results are not accurate.
- Any time you drop or bump the meter.
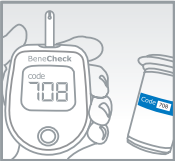- Upon the advice of the healthcare professional.
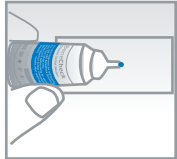
Directions :
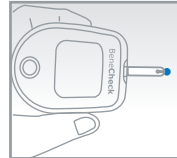
1. Insert a test strip and immediately cover the vial to keep the other test strips in dry condition. The meter will turn on automatically.

2. After "CH" and " " appear on the screen, the ambient temperature and code number will follow. Be careful to make sure the code number is the same as the code number marked on test strip vial.

3. A blood drop symbol " " blinking on the screen means the system is ready for sample loading.

4. Please shake well and discard the first three drops of control solution, then drop some control solution onto a clean surface.

5. Touch the sample inlet of the test strip to the drop of control solution until the meter sounds a "beep". The screen will display a countdown from 10 seconds.

6.
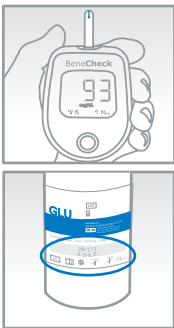
After 10 seconds the screen will display the control test results. Compare the results to the control range listed on the test strip vial.

Note :
- Do not reuse the test strips.
- Newly opened vial of control solution and test strips must be marked with the opening date.
- Close the test strip vial lid tightly after use.
- Do not use BeneCheck Blood Glucose Monitoring System to do any test until you can get the control test result falls within the range listed on the test strip vial.
- If the test results fall outside the control range, please refer to Chapter 8 for trouble shooting.

Chapter 3 How to perform a Blood Glucose Test

3.1 Before Testing

Please follow the step-by-step instructions to ensure accurate test results.

Materials required to perform a blood glucose test include :

- BeneCheck Blood Glucose Meter
- BeneCheck Blood Glucose Test Strip
- Lancing Device / Lancet
- Tissue or cotton ball with 75% ethanol for wiping blood sampling area after test, or simply wash hands with soap and water thoroughly before and after test for disinfection.

Directions :

1. Take a test strip and immediately cover the vial to keep the other test strips in dry condition.

2. Fully insert the contact bar of the test strip into the test port of the meter. The meter will turn on automatically.
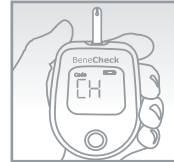
3. After " CH " and " ▭▭▷ " appear on the screen, the code number will follow.
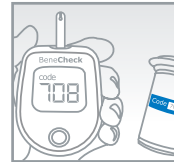
4. Check the code number on the screen is the same as the one on the test strip vial. If not, remove the test strip and recode the meter.

Note :
- The blood glucose test must be performed within 3 minutes, otherwise the meter will be turned off automatically. If turned off, remove and re-insert the test strip to do the test again.
- Test strips cannot be reused. If a used test strip is inserted, a warning message " E-U " will display on the screen. Always use new test strips.
- If the wrong end of the test strip is inserted, or if the test Strip is inserted backwards the Meter will not activate.

⚠️ **Warning :**
- Lancet cannot be reused.
- Please always use certified lancets to ensure safety.

3.2 Perform the Blood Glucose Test
Directions :
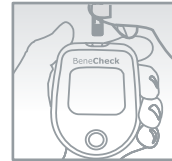
1. Insert the BeneCheck Blood Glucose Test Strip and take a blood sample according to the instructions for lancing device in the system.
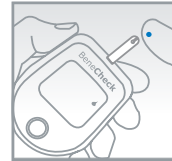
2. Touch the sample inlet of the test strip to the drop of blood sample until the meter sounds a "beep" that means the sample is drawn into the strip successfully.

3. The screen will display a countdown from 10 seconds. After 10 seconds the screen will display the glucose results.

Note :
- Please complete the test procedures within 3 minutes or the meter will automatically turn off.
- Do not apply the blood sample on the test strip anywhere other than the sample inlet.
- Do not apply the blood sample to a same test strip twice, it will cause inaccurate test results.

3.3 Care after the Test
Directions :
1. Follow the instructions for lancing device to treat and discard the used disposable lancet into an appropriate sharps or biohazard container.
2. After performing a test, remove the test strip and meter will automatically turned off.
3. Record the test result and date in your personal diabetes diary.

Note :
- Please check your system performance regularly or when you suspect your test result is inaccurate.
- Dropping, bumping or other violent impact may damage the meter or cause malfunction.
- Do not use the meter in an environment with possible magnetic, electromagnetic, and radioactive interferences.

Warning :
- Do not disassemble the meter for any reason.
- Please follows local regulations to discard used test strips and lancets.
- Used test strips, lancets and any other materials which have been in contact with blood should be treated as potential biohazards. If a user has an infectious disease, the used test strips and other materials could be sources of infection.

Chapter 4 Meter Memory Function

The BeneCheck Meter automatically stores up to 180 records, both blood glucose test results and control test results, each time a test is performed. It also provides you with 7-, 14-, 21- and 28-day averages of the blood glucose test results.
The memory counts up from M01 through M180. Please follow these directions to recall stored test results.

Directions :
1. Make sure that no test strip is inserted in the meter.
2. Press the "Front Button" once to turn the meter on. A full display will appear on screen after a short "beep" sound.
3. Press the "Front Button" once again before the code number appears. The 7-day average (7 DAY.A) will display on the screen.
4. Followed by 14-, 21- and 28-day average when press the "Front Button" repeatedly.
5. After the 28-average, the latest stored result M01 appears on the screen. The memory number increases progressively each time the button is pressed till M180.

6. To turn the meter off, press the "Front Button" for over 3 seconds and the meter will make a long "beep" sound. The meter will also automaticallyshut down after 3 minutes.

Note :
- Please complete the test procedures within 3 minutes or the meter will automatically turn off.
- Do not apply the blood sample on the test strip anywhere other than the sample inlet.
- Do not apply the blood sample to a same test strip twice, it will cause inaccurate test results.

Chapter 5 How to Set the Glucose Measurement Units

Directions :
1. Make sure that no test strip is inserted in the meter.
2. Open the battery cover of the meter, press "Setting Button" once then a blinking number "0x" will appear on Screen. (See Fig.1-3)

3. Press "Setting Button" repeatedly until the glucose unit "mg/dL" or "mmol/L" blinks on the Screen. Press "Front Button" will switch between "mg/dL" and "mmol/L". (See Fig.4a&4b)
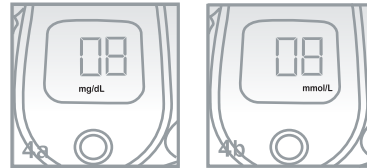
4. Press the setting button once will shift to temperature setting. Press "Setting Button" again will finish the setting and turns off automatically.

Note :
● The setting items of the meter is listed as follows. Please be careful to set the desired glucose unit.

Year → Month → Day → Hour → Minute → Glucose Unit (mg/dL - mmol/L) → Temperature (˚C/ ˚F) → Meter OFF
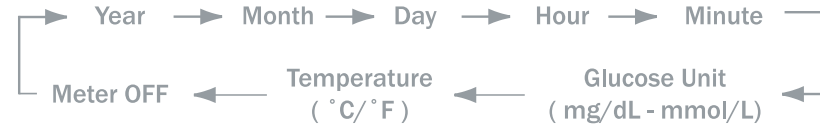
Chapter 6 Storage and Handling of Meter and Strips

Due to sensitive to heat and humidity, the performance of test strips may be affected by improper storage and handling. Please store the test strips and meter carefully according to the specifications listed in Chapter 9.

Note:
1. Store the meter, code strip, test strips and control solution at room temperature. Do not expose them beyond the range described in Chapter 9.
2. Do not freeze or refrigerate the meter and strips.
3. Keep the meter clean by wiping the exterior of the meter with a tissue or lint-free cloth.

Chapter 7 Icon and Alert Tones

7.1 Icon on the Screen
The vivid and clear information icons on the screen are helpful and convenient. In addition to providing accurate blood glucose test results, the icon design on the screen are easy to understand at a glance and will save you the effort of carrying the User's Manual for reference.

Code Number Icon
Memory Number Icon
Strip Loading Icon
Blood Loading Icon
Result Area
Battery Icon
System Check Icon
Temperature Icon
Average Icon
Unit Icon

Code M mg/dL mmol/L DAY.A AM
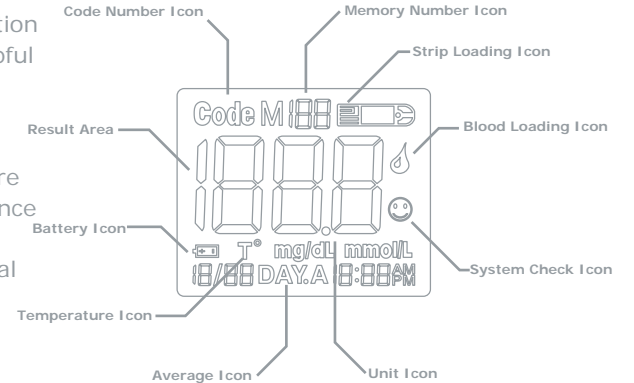
7.2 Alert Tones
- Normal Alert Sound : a short "beep"
- Warning Alert Sound : 5 short "beeps"
- Turning On/Off Alert Sound : a long "beep"

Chapter 8 Error Message and Trouble Shooting

Message	Cause	Solution
E-O	There may be a problem with the meter or code strip.	Repeat the test with a new code strip. If the problem persists, please contact the dealer for service.
E-9	The test strip may be removed after applying blood to the absorbent hole.	Review the instructions and try again with a new test strip. If the problem persists, please contact the dealer for service.
E-A	There is a problem with the meter.	Review the instructions and try again with a new test strip. If the problem persists, please contact the dealer for service.
E-b	The power of the battery is too low to run a test.	Replace the battery at once.

Message	Cause	Solution
E-C	Usage of the code strip was inserted improperly, damaged, or incorrect.	Check that the code number on the meter display matches the code number on the test strip vial. Code the meter or retest as necessary. If the error message appears again, please contact the dealer for service.
E-t & Tm Sign	The temperature was below or above the system operating range.	Repeat the test after the meter and the test strip have reached the temperature within the operating range.
EU	It could be caused by a used test strip or a temporary or permanent electronic problem.	Repeat the test with a new test strip. If the error message appears again, please contact the dealer for service.

Message	Cause	Solution
Hi	1. Blood glucose level is higher than 600 mg/dL. 2. Test strip has problem.	1. Review the instructions and try again with a new test strip. 2. Check the test strip vial to make sure that it is not marked beyond the expiration date.
Lo	1. Blood glucose level is lower than 20 mg/dL. 2. Test strip has problem.	1. Review the instructions and try again with a new test strip. 2. Check the test strip vial to make sure that it is not marked beyond the expiration date.

Chapter 9 Specifications

System Accuracy	: ± 20% at glucose level > 75 mg/dL
Test Sample	: Capillary whole blood
Measuring Time	: Less than 10 seconds
Measuring Range	: 20 - 600 mg/dL (1.1 - 33.3 mmol/L)
Sample Volume	: About 1 - 1.5 µL
Strip Storage Condition	: 10 - 30°C
Operation Temperature	: 10 - 40°C
Relative Humidity	: Less than 95%
Memory	: 180 test results
Battery Type	: One 3V (CR2032) lithium battery
Battery Life	: Approximately 1,000 tests
Dimensions	: 61*77*19 mm
Weight	: About 47g (batteries not included)

Chapter 10 Limitations

Please observe the following limitations for obtaining accurate results of BeneCheck Blood Glucose Monitoring System :

1. For In-vitro diagnostic use only (External use only).

2. Do not dispose test strips in high humidity or direct sunlight. Don't freeze the strips.

3. BeneCheck Blood Glucose Test Strip is for single use only, please do not reuse the test strip.

4. Handle the strip with clean and dry hands; lancing site for the test should be cleaned and dried thoroughly.

5. Do not perform the test while a cell phone is used beside; prevent the electronic signal interference.

6. Oxygen concentration low in air may cause the test inaccurate; there is no effect from altitude up to 10,000 feet above sea level.

7. Medical therapy for intravenous injection, such as immunoglobulin preparations and peritoneal dialysis solutions, containing sugar compounds may cause higher test results.

8. Hematocrit (Hct) range from 30-55% is acceptable. Hct less than 30% may cause elevated results. Hct above 55% may cause reduced glucose results versus a whole blood reference.